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No. 04-623

IN THE

Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, *et al.*,

Petitioners,

v.

STATE OF OREGON, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF *AMICUS CURIAE* OF THE THOMAS MORE SOCIETY IN SUPPORT OF PETITIONERS

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Interest of *Amicus Curiae*[*]

The Thomas More Society is a non-sectarian 501(c)(3) public charity based in Chicago, Illinois, and is incorporated as an Illinois not-for-profit corporation. Founded in 1997, the Thomas More Society was established to help meet the burgeoning legal needs of the pro-life movement and, in particular, to defend those who face legal battles as a result of their commitment to the protection of basic civil rights for the most vulnerable and defenseless members of our society, innocent prenatal human beings. The Thomas More Society provides legal advice and assistance to those who face harassment, employment discrimination, unjust treatment or prosecution as a result of their pro-life position.

The Thomas More Society approves of appropriate public policies to protect innocent human life at all stages of life, from conception to natural death. Consistent with its mission and the respect for human life which that mission implies, the Thomas More Society opposes state-sanctioned physician-assisted suicide and supports the Attorney General's rule prohibiting the prescription of controlled substances to facilitate physician-assisted suicide. A ruling by this Court affirming the Ninth Circuit would undermine enforcement of the Controlled Substances Act and compromise the authority of the Attorney General to determine that certain uses of controlled substances, including the prescription of such substances for the purpose of assisting an individual in committing suicide, are not medically legitimate, are not consistent with the public interest and should be prohibited, notwithstanding contrary state law. To assist the Court in addressing the issues presented, *amicus* submits this brief.

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[*] Letters of consent have been filed with the Clerk. None of the counsel for the parties authored this brief in whole or in part, and no one other than *amicus* or its counsel has contributed money or services to the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

For more than thirty years, Department of Justice regulations implementing the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.* (2000), have provided that a prescription for drugs covered by the Act is valid only if issued for a "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (2004). On November 6, 2001, the Attorney General issued an interpretive ruling, effective November 9, 2001, to clarify that a prescription of a controlled substance issued for the purpose of assisting an individual in committing suicide is not one made for a "legitimate medical purpose" within the meaning of § 1306.04(a), and that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." 66 Fed. Reg. 56,608. "Such conduct by a physician registered to dispense controlled substances," the Attorney General warned, "may 'render his registration * * * inconsistent with the public interest' and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4)." *Id.*, quoting 21 U.S.C. § 824(a)(4). The Attorney General specifically noted that this conclusion applies "regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted." *Id.*

Respondents, the State of Oregon, which allows physician assisted suicide, OR. REV. STAT. § 127.800 *et seq.* (2003), and others, challenged the interpretive rule in the United States District Court for the District of Oregon. The district court held the rule invalid and enjoined petitioners "from enforcing, applying, or otherwise giving any legal effect" to the rule. *Oregon v. Ashcroft*, 192 F.Supp.2d 1077, 1080 (D. Or. 2000). On appeal, the court of appeals held that

the district court had lacked jurisdiction over respondents' action and treated the case as a petition for review under 21 U.S.C. § 877 that had been mistakenly filed in the district court and transferred to the court of appeals. *Oregon v. Ashcroft*, 368 F.3d 1118, 1120-21 (9th Cir. 2004). On the merits, a divided court granted the petitions for review and "continued" the district court's injunction. *Id.* at 1131.

The majority held that the Attorney General lacked statutory authority to issue the rule in question. The interpretive rule "violates the 'clear statement' rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress." 368 F.3d at 1123. With respect to the first reason, which is the subject of this brief, the court noted that the States, not the federal government, are "'the primary regulators of professional [medical] conduct.'" *Id.* at 1124, quoting *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002). Accordingly, "state governments bear the primary responsibility for evaluating physician assisted suicide . . . ." *Id.* The Attorney General's interpretive rule, however, "interferes with Oregon's authority to regulate medical care within its borders" by "criminalizing medical practices specifically authorized under Oregon law [*i.e.*, the use of physician prescribed controlled substances to assist a terminally ill patient in committing suicide]." *Id.* This "interference," according to the majority, "'alter[s] the usual constitutional balance between the States and the Federal Government.'" *Id.*, quoting *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (internal quotation marks and citation omitted). "Under these circumstances," the court determined, "'it is incumbent upon the federal courts to be certain of Congress' intent' before finding that federal authority supercedes state law." *Id.* at 1124-25, quoting *Gregory*, 501 U.S. at 460 (internal quotation marks and citation omitted).

The majority held that in the absence of an "'unmistakably clear'" authorization from Congress, "the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care." *Id.* at 1125, quoting *Gregory*, 501 U.S. at 460 (internal quotation marks and citation omitted). The court found "no indication–much less an 'unmistakably clear' indication–that [Congress] intended to authorize the Attorney General to regulate the practice of physician assisted suicide." *Id.* "By attempting to regulate the practice of physician assisted suicide, the [interpretive rule] invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice." *Id.* The majority concluded that the interpretive rule "violates the clear statement rule" because "Congress has not clearly authorized such an intrusion [into the State's authority to regulate medical practice]." *Id.*

Senior Judge Wallace dissented. The majority's reliance on the "clear statement" rule was misplaced and ignored controlling Supreme Court precedents, as well as the text of the Controlled Substances Act itself. 368 F.3d at 1136-37. Although "federal law occasionally incorporates state-law definitions by reference, *id.*, at 1136, citing *De Sylva v. Ballentine*, 351 U.S. 570, 580-82 (1956) (defining the word "children" in a federal statute according to state law), "recourse to state law is the exception rather than the norm." *Id.* "[T]he general assumption [is] that 'in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute [does] not mak[e] the application of the federal act dependent on state law.'" *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989), quoting *Jerome v. United States*, 318 U.S. 101, 104 (1943).

The dissent noted that there is no language in the Controlled Substances Act suggesting that Congress intended

the Act to be dependent upon state law. "State law may be *relevant* to certain provisions of the . . . Act," 368 F.3d at 1137, citing 21 U.S.C. § 823 (f) (instructing the Attorney General to consider state-law violations when deciding whether a physician's registration would be contrary to the public interest), "but nothing in the Controlled Substances Act plainly evinces a congressional intent to define 'the public interest' solely according to state law." *Id.* Section 823 "instructs the Attorney General to identify acts 'inconsistent with the public interest' by reference to a variety of sources, including a physician's federal conviction record, compliance with 'Federal . . . laws relating to controlled substances,' and 'other conduct which may threaten public health and safety.'" *Id.*, quoting 21 U.S.C. § 823. Thus, "[t]he majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band's* 'plain indication' rule and contravenes Congress' clearly expressed intent." *Id.* *Amicus curiae* concurs with Senior Judge Wallace's dissent.

1. The majority's reliance on *Gregory v. Ashcroft*, 501 U.S. 452 (1991), was clearly misplaced. At issue in *Gregory* was whether the Age Discrimination in Employment Act (ADEA), 29 U.S.C. § 621 *et seq.* (2000), applied to state court judges who had been appointed to office by the Governor of Missouri and who were required to retire by age 70 by a provision of the Missouri Constitution. The Court noted that the mandatory retirement provision "goes beyond an area traditionally regulated by the States; it is a decision of the most fundamental sort for a sovereign entity. Through the structure of the government, and the character of those who exercise government authority, the State defines itself as a sovereign." 501 U.S. at 460. If Congress intends to alter the "'usual constitutional balance between the States and the Federal Government,'" it must make its intention to do so

"'unmistakably clear in the language of the statute.'" *Id.*, quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 242 (1985). The "plain statement" rule applies to "state decisions that 'go to the heart of representative government.'" *Id.* at 461, quoting *Sugarman v. Dougall*, 413 U.S. 634, 647 (1973). In *Gregory*, the Court determined that the ADEA was at least ambiguous whether a state judge is an "appointee on the policymaking level," within the meaning of 29 U.S.C. § 630(f), and therefore excluded from the scope of the Act. *Id.* at 467. In the absence of a "plain indication" that Congress intended to include appointed judges within the scope of the Act, the Court declined to attribute such an intent to Congress. *Id.* at 470.

The court of appeals gave *Gregory* an overly broad reading. The "plain statement" rule, properly understood, "is limited to federal laws impacting a [S]tate's self-identification as a sovereignty," not to a State's "substantive policy choice[s]." *United States v. Lot 5, Fox Grove, Alachua County, Florida*, 23 F.3d 359, 362 (11th Cir. 1994), *cert. denied*, 513 U.S. 1076 (1995). Oregon's decision to legalize physician-assisted suicide, however, is simply a "substantive policy choice" on behalf of the State, not part of the State's "self-identification as a sovereignty." The "regulation of medical care" may be an area "traditionally reserved for state authority," 368 F.3d at 1125, but that is not enough to invoke the "plain statement" rule. In *Gregory*, the Court stressed that the mandatory retirement provision in the Missouri Constitution "*goes beyond an area traditionally regulated by the States*, ..." 501 U.S. at 460 (emphasis added). Moreover, although the regulation of the practice of medicine may be a matter "traditionally reserved for state authority," the same cannot be said of the regulation of controlled substances which, since adoption of the Harrison Narcotics Act of 1914, 38 Stat. 785, has been a matter of profound *federal* interest.

2. The majority's application of the "plain statement" rule to the Controlled Substances Act dramatically undermines the Attorney General's authority to enforce the Act and federal drug control policy. According to the majority, absent an "unmistakably clear" indication from Congress that it intended to authorize the Attorney General to regulate the specific purposes for which controlled substances may be prescribed (*e.g.*, physician-assisted suicide), each State may decide for itself the purposes for which such substances may be prescribed. Thus, under the majority's holding, a State could authorize controlled substances to be used for a variety of purposes–facilitating religious expression, enhancing athletic performance, inducing euphoria, providing recreation, operating unauthorized narcotic drugs maintenance programs and conducting unregulated research (with Schedule I substances), as well as assisting suicide–and the Attorney General would be powerless to do anything about it. The State's authorization of controlled substances for those purposes would effectively preclude the Attorney General from taking any action–civil, administrative or criminal–against a registrant acting in compliance with state law. A holding that leads to such extraordinary results cannot be reasonable.

Adoption of the majority's reasoning would inevitably result in the Balkanization of medical practice, in which each State would be free to decide for itself whether a controlled substance could be used for a given purpose, no mater how unethical, unorthodox, untested or unusual. Under the majority's holding, conduct that otherwise could result in suspension or revocation of a physician's registration to dispense federal controlled substances, or even criminal prosecution, would be immune from federal control by virtue of state law authorizing the specific purposes for which controlled substances may be prescribed. That is clearly not what Congress intended in enacting the Controlled Substances Act.

ARGUMENT

I. THE COURT OF APPEALS ERRED IN RELYING ON THE "PLAIN STATEMENT" RULE OF *GREGORY V. ASHCROFT*, 501 U.S. 452 (1991), TO ENJOIN THE ATTORNEY GENERAL FROM ENFORCING AN INTERPRETIVE RULE FORBIDDING THE PRESCRIPTION OF CONTROLLED SUBSTANCES FOR THE PURPOSE OF ASSISTING AN INDIVIDUAL IN COMMITTING SUICIDE.

The court of appeals held that the Attorney General was powerless to proscribe the prescription of controlled substances for the purpose of assisting an individual in committing suicide in the absence of an "unmistakably clear" expression of Congressional intent authorizing him to so interpret the Controlled Substances Act. 368 F.3d at 1125. In so ruling, the majority relied principally on this Court's decision in *Gregory v. Ashcroft*, 501 U.S. 452 (1991). *Id.* at 1124-25. That reliance was clearly misplaced.

1. Under well-established precedent, "the general assumption [is] that 'in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent on state law.'" *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989), quoting *Jerome v. United States*, 318 U.S. 101, 104 (1943). "One reason for this rule of construction is that federal statutes are generally intended to have uniform nationwide application." *Id.*, citing *Jerome*. "A second reason for the presumption against the application of state law is the danger that 'the federal program would be impaired if state law were to control.'" *Id.* at 44, quoting *Jerome*, 318 U.S. at 104. Both reasons apply here.

First, as Senior Judge Wallace noted in his dissent, 368 F.3d at 1137, there is no language in the Controlled Substances Act suggesting that Congress intended the Act to be dependent upon state law. Although "State law may be *relevant* to certain provisions of the . . . Act," *e.g.*, 21 U.S.C. § 823(f) (instructing the Attorney General to consider state law violations when deciding whether a physician's registration would be contrary to the public interest), "nothing in the Controlled Substances Act plainly evinces a congressional intent to define 'the public interest' solely according to state law." *Id.* Section 823 "instructs the Attorney General to identify acts 'inconsistent with the public interest' by reference to a variety of sources, including a physician's federal conviction record, compliance with 'Federal . . . laws relating to controlled substances,' and 'other conduct which may threaten public health and safety.'" *Id.*, quoting 21 U.S.C. § 823. Thus, "[t]he majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band's* 'plain indication' rule and contravenes Congress' clearly expressed intent." *Id.*[1]

This Court has recognized that in enacting the Controlled Substances Act, Congress intended to provide "a comprehensive *federal* scheme for the control of drug abuse." *Gooding v. United States*, 416 U.S. 430, 449 (1974) (emphasis added). To be effective, enforceable and uniform, such a scheme must rely on a general standard of medical

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[1] The majority also ignored its own precedent. *See United States v. Rosenberg*, 515 F.2d 190, 198 n.14 (9th Cir. 1975) (rejecting the argument that a federal prosecution under the Controlled Substances Act could not proceed unless and until there had been a finding that the defendant's conduct was unauthorized under state law), *cert. denied*, 423 U.S. 1031 (1975).

care that exists throughout the United States, not one that turns on the peculiarities of each State's law. *See United States v. Moore*, 423 U.S. 122, 139 (1975) (approving jury instruction that, under the Controlled Substances Act, prescriptions must be made "in accordance with a standard of medical practice generally recognized and accepted in the United States").[2]

Second, for the reasons developed in more detail in the following argument, it is evident that the purposes of the Controlled Substances Act would be seriously undermined if, as the majority held, state law were to control what constitutes the permissible uses of substances subject to the Act. Suffice it to say here that the very concept of a *federal* controlled substances act would be compromised if *state* law ultimately determined the permissible uses of controlled substances. *See United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (rejecting claim that Californians who used marijuana for medical purposes "upon the recommendation or approval of a physician" in compliance with California law were exempt from the prohibitions of the Controlled Substances Act which classifies marijuana as a Schedule I substance with no recognized medical use).

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[2] *See also United States v. Norris*, 780 F.2d 1207, 1209 & n. 2 (5th Cir. 1986) ("a standard medical practice may [not] be based on an entirely subjective standard" but must be one "recognized and accepted in the United States"); *United States v. Vamos*, 797 F.2d 1146, 1153 (2nd Cir. 1986) ("[t]o permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken our drug laws in a critical area"), *cert. denied*, 479 U.S. 1036 (1987); *United States v. Kirk*, 584 F.2d 773, 785 (6th Cir. 1978) (relying on "generally acceptable standards of medical practice for issuing prescriptions"), *cert. denied*, 439 U.S. 1048 (1978); *United States v. Boettjer*, 569 F.2d 1078, 1081 (9th Cir. 1978) (same), *cert. denied*, 435 U.S. 976 (1978); *United States v. Green*, 511 F.2d 1062, 1073 (7th Cir. 1975) (same)

2. The majority erred in relying on *Gregory v. Ashcroft* to circumvent the "plain indication" rule of *Mississippi Band*. The issue in *Gregory* was whether the ADEA, 29 U.S.C. § 621 *et seq.*, which makes it unlawful for an "employer" "to discharge any individual" who is at least 40 years old "because of such individual's age," 29 U.S.C. §§ 523(1), 631(a), applies to state court judges who had been appointed to office by the Governor of Missouri and who were subject to mandatory retirement at age 70 by art. V, § 26, of the Missouri Constitution. MO. CONST. art. V, § 26 (West 1995).

The Court began its analysis of the issue by noting that art. V, § 26, "goes beyond an area traditionally regulated by the States; it is a decision of the most fundamental sort for a sovereign entity. Through the structure of its government, and the character of those who exercise government authority, a State defines itself as a sovereign." 501 U.S. at 460. The States' power to "'prescribe the qualifications of their own officers'" is "'essential to [their] independence'" and "'should be exclusive and free from external interference, except so far as plainly provided by the Constitution of the United States.'" *Id.*, quoting *Taylor v. Beckham*, 178 U.S. 548, 570-71 (1900).

The Court observed that "Congressional interference with [the] decision of the people of Missouri, defining their constitutional offices, would upset the usual constitutional balance of federal and state powers." 501 U.S. at 460. For that reason, "'it is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides' this balance." *Id.*, quoting *Atascadero State Hospital v. Scanlon*, 473 U.S. 234, 243 (1985). Where Congress intends to alter the "'usual constitutional balance between the States and the Federal Government,'" it must makes its intention to do so "'unmistakably clear in the language of the

statute." *Id.*, quoting *Atascadero*. "This plain statement rule," the Court explained, "is nothing more than an acknowledgment that the States retain substantial powers under our constitutional scheme, powers with which Congress does not readily interfere." *Id.* at 461.

The Court referred to a recent line of authority in which it has "acknowledged the unique nature of state decisions that 'go to the heart of representative government.'" *Gregory*, 501 U.S. at 461, quoting *Sugarman v. Dougall*, 412 U.S. 634, 647 (1973). Under this line of authority, the Court has considered the authority of state and local governments to prohibit aliens from public employment and has applied a lower standard of review than strict scrutiny "when evaluating the validity of exclusions [from public employment] that entrust only to citizens important elective and nonelective positions whose operations 'go to the heart of representative government.'" *Bernal v. Fainter*, 467 U.S. 216, 221 (1984), quoting *Sugarman*, *supra*. The "political function" cases recognize "the authority of the people of the States to determine the qualifications of their most important government officials." *Gregory*, 501 U.S. at 463.

Turning to the question at hand, the Court noted that the ADEA excludes from the definition of employee "an appointee on the policymaking level" chosen by "any person elected to public office in any State . . . ." *Gregory*, 501 U.S. at 465, quoting 29 U.S.C. § 630(f). After reviewing the authority of Missouri state court judges, including their power to interpret and develop the common law, the Court found that it was "at least ambiguous whether a state judge is an 'appointee on the policymaking level,'" and thus excluded from the coverage of the Act. *Id.* at 467. Because Congress did not make it clear that judges are included, the Court concluded that the Act does not cover them. *Id.* at 470.

3. *Gregory* has no application to the Controlled Substances Act. First, in *Gregory*, the Court stressed that the state constitutional provision at issue "*goes beyond an area traditionally regulated by the States*, ..." 501 U.S. at 460 (emphasis added). *See City of Edmonds v. Oxford House*, Inc., 514 U.S. 725, 732 n. 5 (1995) (emphasizing this aspect of *Gregory*). Thus, the majority's observation that the "regulation of medical care" is "an area of law traditionally reserved for state authority," 368 F.3d at 1125, does not, in and of itself, implicate the "plain statement" rule. Second, although regulation of the practice of medicine may be a matter "traditionally reserved for state authority," the same certainly cannot be said of the regulation of controlled substances. For more than 90 years, from adoption of the Harrison Narcotics Act of 1914, 38 Stat. 785, through enactment of the Controlled Substances Act of 1970, 84 Stat. 1236, § 100 *et seq.*, the regulation of controlled substances has been a matter of continuing and uninterrupted *federal* interest.[3]

Gregory's "plain statement" rule does not apply unless "provisions [of federal law] are ambiguous *and* state

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[3] Indeed, one commentator has pointed out that "[a]lthough the Harrison Narcotics Act was certainly an important milestone in the history of drug control, it hardly represented the first use of the criminal law in this area, even at the federal level [citing the Pure Food and Drug Act of 1906, 34 Stat. 768, and various national and international efforts to ban opium smoking and importation of opium for smoking before 1914]." Joseph F. Spillane, "The Road to the Harrison Narcotics Act: Drugs and Their Control, 1875-1918," FEDERAL DRUG CONTROL[:] THE EVOLUTION OF POLICY AND PRACTICE at 10 (Haworth Press 2004) (Jonathon Erlen & Joseph F. Spillane, Eds.). *See also* H.R. 91-1444, 91st Cong., 2nd Sess. (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4571 (noting that since 1914, "the Congress has enacted more than 50 pieces of legislation relating to control and diversion, from legitimate channels, of those drugs referred to as narcotics and dangerous drugs").

sovereignty is at issue, ..." *E.E.O.C. v. Commonwealth of Massachusetts*, 987 F.2d 64, 69 (1st Cir. 1993) (*Gregory* did not prevent the E.E.O.C. from using the ADEA to overturn a Massachusetts law that required state and local officials and general employees who are seventy years old or older to take and pass a medical examination as a condition of continued employment). For the reasons set forth above, the provisions of the Controlled Substances Act are not ambiguous and state sovereignty is not at issue in the regulation of the use of federally controlled substances.

The Eleventh Circuit has held that "the *Gregory* plain statement rule is limited to federal laws impacting a [S]tate's self-identification as a sovereignty." *United States v. Lot 5, Fox Grove, Alachua County, Florida*, 23 F.3d 359, 362 (11th Cir. 1994) (federal civil forfeiture law preempts Florida's constitutional homestead right). In *United States v. Lot 5*, the court of appeals noted that Florida's homestead protection is "a substantive policy choice, not a means of sovereign definition." *Id.* So, too, Oregon's decision to decriminalize the use of controlled substances for physician assisted suicide simply represents a "substantive policy choice" of the State and is not a means of "sovereign definition."[4]

This Court has intimated (and lower courts have held) that "exercising ultimate control over the management of

[4] Nothing in the Attorney General's interpretive rule affects the legality of assisted suicide under Oregon law, other than the use of controlled substances to facilitate suicides. Other means of assisting suicide, *e.g.*, inhalation of gasses or ingestion of substances not covered by the Controlled Substances Act, would remain available options, as the dissent noted. 368 F.3d at 1134-35 (Wallace, Senior Judge, dissenting). The rule does not prevent "[s]tate legislators [from] authoriz[ing] alternative methods for assisting suicide that do not involve the prescription of controlled substances." *Id.* at 1148.

state prisons, like establishing the qualifications of state government officials, is a traditional and essential function subject to the plain statement rule of *Gregory*." *Pennsylvania Dep't of Corrections v. Yeskey*, 524 U.S. 204, 209 (1998).[5] The Court has also relied, in part, on *Gregory* in holding that States have an "essential sovereign interest in the security and stability of title to land." *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 544 n. 8 (1994). A state law decriminalizing assisted suicide, however, affects only private conduct and does not trench upon the "sovereign interest[s]" of the State.

Gregory's "plain statement" rule has been held *not* to apply to federal labor regulation of "the relationship between a local government employer and its employees," *Nicols v. City of Chicago*, 789 F.Supp. 1438, 1446 (N.D. Ill. 1992), or to ERISA's impact on state labor statutes, even though such matters "traditionally [have been] regulated at the state level." *Associated Builders & Contractors v. Perry*, 817 F.Supp. 49, 53-54 n.3 (E.D. Mich. 1992). In the latter case, the district court noted that state laws regulating labor relations "certainly do not rise to the level of 'the most fundamental sort for a sovereign entity.'" *Id.*, quoting *Gregory*, 501 U.S. at 460. The plain statement rule has also been held not to apply to a provision of the Voting Rights Act that "impinges on the authority of [S]tates to employ certain election practices," but not on their authority "to set

[5] *See Torcasio v. Murray*, 57 F.3d 1340, 1345 (4th Cir. 1995) ("the management of state prisons is a core state function"); *Amos v. Maryland Dep't of Public Safety and Correctional Services*, 126 F.3d 589, 600 (4th Cir. 1998) (adhering to *Torcasio*), *vacated and remanded on other grounds*, 524 U.S. 935 (1998); *Crawford v. Indiana Dep't of Corrections*, 115 F.3d 481, 485-86 (7th Cir. 1997) (same); *Yeskey v. Commonwealth of Pennsylvania Dep't of Corrections*, 118 F.3d 168, 173 (3rd Cir. 1997) (same), *aff'd*, 524 U.S. 204 (1998).

qualifications for their elected officials." *League of United Latin American Citizens Council No. 4434 v. Clements*, 986 F.2d 728, 759 (5th Cir. 1993). *See also Gately v. Commonwealth of Massachusetts*, 2 F.3d 1221 (1st Cir. 1993) (declining to apply *Gregory's* "plain statement" rule to the ADEA's invalidation of state policy mandating retirement of state police). Oregon's interest in allowing controlled substances to be used in facilitating physician-assisted suicide is no greater than any of the state interests asserted, but found wanting, in the foregoing cases.

The court of appeals erred in relying on the "plain statement" rule of *Gregory v. Ashcroft* to enjoin the Attorney General from enforcing his interpretive rule barring the use of controlled substances for the purpose of assisting an individual in committing suicide. Because that error was central to the court's analysis, its judgment should be reversed.

II. ADOPTION OF THE COURT OF APPEALS' HOLDING WOULD UNDERMINE ENFORCEMENT OF THE CONTROLLED SUBSTANCES ACT AND COMPROMISE THE ATTORNEY GENERAL'S AUTHORITY TO DETERMINE THAT CERTAIN USES OF CONTROLLED SUBSTANCES ARE NOT MEDICALLY LEGITIMATE, ARE NOT CONSISTENT WITH THE PUBLIC INTEREST AND SHOULD BE PROHIBITED, NOTWITHSTANDING CONTRARY STATE LAW.

The holding of the court of appeals, if adopted by this Court, would undermine enforcement of the Controlled Substances Act and compromise the Attorney General's authority to determine that certain uses of controlled substances, including the prescription of such substances for the purpose of assisting an individual in committing suicide,

are not medically legitimate, are not consistent with the public interest and should be prohibited, notwithstanding contrary state law. Under the court of appeals' holding, the Attorney General may not prohibit the prescription, dispensing or administration of controlled substances for any purposes allowed by state law, in the absence of an "unmistakably clear" indication from Congress authorizing him to do so. 368 F.3d at 1125.[6] The possible consequences of such a holding, if not reversed by this Court, are not difficult to foresee.

Facilitating Religious Expression

For forty years, first by regulation, 21 C.F.R. § 166.3(c), recodified as 21 C.F.R. § 1307.31 (2004), later by statute, 42 U.S.C. § 1996a (2000), federal law has allowed the traditional religious use of peyote by members of Indian tribes. The stems of peyote, a variety of cactus, "contain mescaline which has a hallucinogenic effect when ingested." *Peyote Way Church of God, Inc. v. Thornburgh*, 922 F.2d 1210, 1212 (5th Cir. 1991).[7] The exemption in federal law for the religious use of peyote by members of Indian tribes has

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[6] Respondents fully endorse this holding. *See* Or. Br. in Op. 15 ("the CSA does not contain a 'clear statement' of intent to authorize the Attorney General to determine what uses state-licensed doctors may make of substances that concededly have approved medical uses"); Rasmussen Br. in Op. at 15-18 (same); Patient Br. in Op. 4 (no evidence that Congress, in enacting the CSA, "'intended . . .. to override a state's determination as to what constitutes legitimate medical practice in the absence of a federal law prohibiting that practice'") (quoting letter of June 5, 1998, from Attorney General Reno to Hon. Henry Hyde).

[7] Both peyote and mescaline are classified as Schedule I controlled substances. 21 U.S.C. §§ 812(c), Schedule I (c)(11) (mescaline); Schedule I (c)(12) (peyote); 21 C.F.R. §§ 1308.11(d)(21) (mescaline); 1308.11(d)(23) (peyote) (2004).

led to a flurry of lawsuits by other religious groups challenging, on equal protection and other grounds, the law's failure to include exemptions for the religious use of peyote by non-members of Indiana tribes, *see Peyote Way Church of God, supra*, and the religious use of other drugs, particularly marijuana. *See Olsen v. Drug Enforcement Administration*, 878 F.2d 1458, 1461-64 (D.C. Cir. 1989) (Op. of R. Ginsburg, J.) (Ethiopian Zion Coptic Church), and the cases cited therein);[8] *O Centro Espirita Benficiente Uniao do Vegetal v. Ashcroft*, 342 F.3d 1170, 1186 n.4 (10th Cir. 2003) (rejecting equal protection claim that religious use of *hoasca*, a tea containing dimethyltryptamine, a Schedule I hallucinogen, must be protected because "the Native American Church's use of peyote is protected"), *on reh'g*, 389 F.3d 973 (10th Cir. 2004) (*en banc*), *cert. granted*, April 18, 2005, Docket 04-1084.[9]

The foregoing challenges generally have been rejected.[10] Nevertheless, they reflect efforts by some

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[8] *See also Whyte v. United States*, 471 A.2d 1018 (D.C. Ct. App. 1984) (Rastafarian Church); *Leary v. United States*, 383 F.2d 851, 861 & n.11 (5th Cir. 1967) (individual religious use of marijuana), *rev'd on other grounds*, 395 U.S. 6 (1969).

[9] On rehearing, the Tenth Circuit determined that plaintiffs had shown a probability of success in prevailing on the merits of their claim that the prohibition of the religious use of *hoasca* violates the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.* (2000). 389 F.3d at 976 (*per curiam* op.); *id.* at 1004-1011 (Seymour, J., concurring in part and dissenting in part); *id.* at 1018-31 (McConnell, J., concurring).

[10] *But see Native American Church of New York v. United States*, 468 F.Supp. 1247, 1251 (S.D.N.Y. 1979) (ruling that the regulatory exemption for peyote would have to be made "equally available" to "a bona fide religious organization [that] would make use of peyote for sacramental purposes and regard the drug as a deity"), *aff'd mem. op.*, 633 F.2d 205 (2nd Cir. 1980).

religious groups (and their members) to use the courts to broaden the circumstances under which controlled substances may be used for religious purposes. In light of the Ninth Circuit's decision in this case, however, those efforts may be redirected to state legislatures. The States, of course, may choose to grant religious exemptions to their *own* controlled substances laws. What they have not been able to do, until now, is grant religious exemptions to the Controlled Substances Act. But that is effectively what the court of appeals decision permits, possibly with respect to Schedule I controlled substances (for which there is no recognized medical use), and certainly with respect to controlled substances classified under Schedules II through V. Allowing state law to override federal law with respect to the religious use of controlled substances would undermine "the government's interest in the uniform enforcement of the Controlled Substances Act," an interest "of the highest order." *O Centro Espirita Benficiente Uniao do Vegetal v. Ashcroft*, 389 F.3d at 985 (Murphy, J., concurring in part and dissenting in part). *See also, id.*, at 1031 (Hartz, J., dissenting) (the Government has "a compelling interest in uniform application of the Controlled Substances Act"). Yet that is precisely what the Ninth Circuit's decision allows.

Enhancing Athletic Performance

The abuse of anabolic steroids, a Schedule III controlled substance[11] that "promotes muscle growth," 21 U.S.C. § 802(41)(A) (defining term "anabolic steroid"), has received widespread recent attention in Congressional hearings into the use of steroids in professional sports. *See* House Committee on Government Reform, Hearings on Steroid Use in

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[11] 21 U.S.C. § 812(c), Schedule III(e); 21 C.F.R. § 1308.13(f) (2004).

Sports (ongoing).[12] The hearings have disclosed disturbing details about the extent and seriousness of anabolic steroid abuse. Although anabolic steroids have appropriate medical purposes, *e.g.*, "to treat conditions that occur when the body produces abnormally low amounts of testosterone, such as delayed puberty and some types of impotence," and "to treat body wasting in patients with AIDS and other diseases that result in loss of lean muscle mass,"[13] taking steroids for the purpose of enhancing athletic performance is not one of them. "Inappropriate use of anabolic steroids can have serious health consequences," including, in younger steroid abusers, "[the] risk of permanently halting their growth," in males, "a shrinking of their testicles, reduced sperm count, infertility, baldness, development of breasts, and an increased risk for prostate cancer," and in females, "menstrual abnormalities, deepening of the voice, shrinkage of breasts, male-pattern baldness, and an increase in sex drive, acne, body hair and clitoris size."[14] For both men and women, other consequences include "liver and heart disease, stoke, drug dependence, and increased aggression."[15]

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[12] The statements and written testimony of witnesses at the March 17, 2005, hearing may be found at http://reform.house.gov/GovReform/Hearings/Event Single.aspx?EventID1637. The Committee also heard testimony on April 27, 2005.

[13] Statement of Nora D. Volkow, M.D., Consequences of the Abuse of Anabolic Steroids at 2, Testimony Before the Committee on Government Reform, U.S. House of Representatives, March 17, 2005. Dr. Volkow is the Director of the National Institute on Drug Abuse, National Institutes of Health, United States Department of Health & Human Services.

[14] *Id.* at 3, 9.

[15] *Id.* at 3-4.

In one survey conducted in 2003 by the Centers for Disease Control and Prevention, 6.1% of students in grades 9 through 12 reported illegal use of anabolic steroids at least once in their lifetime, up from 2.7% in 1991; a somewhat differently designed study indicated that 79,000 high school seniors reported having abused anabolic steroids last year (2004).[16] In an attempt to address the problem of steroid abuse, Congress recently enacted the Anabolic Steroid Control Act of 2004, 108 Pub. L. 358, 118 Stat. 1661 (2004), bringing many of the abused substances that previously had not been illegal (particularly steroid precursors) within the scope of the Controlled Substances Act.[17] Other medical and psychiatric testimony underscored the severity of the problem of anabolic steroid abuse.[18]

Under the court of appeals' holding, however, if a State decided to authorize the use of anabolic steroids for purposes which would not generally be regarded as medical in nature, *e.g.*, enhancing athletic performance, body building or weight training, the Attorney General would not be able take any action–civil, administrative or criminal–against registrants who dispensed drugs for those purposes The State's sanctioning of the use of anabolic steroids for such questionable purposes, no matter how unethical or unusual, would effectively bar federal enforcement of the Controlled Substances Act, just as it has with Oregon's use of controlled substances in its experiment with physician-assisted suicide.

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[16] *Id.* at 7.

[17] *Id.* at 6-7.

[18] *See* Statements of Kirk J. Brower, M.D. and Gary I. Wadler, M.D., March 17, 2005

Inducing Euphoria

There is no generally accepted medical use of controlled substances to induce a state of euphoria.[19] Yet, under the Ninth Circuit's holding, if a State decided to authorize physicians to prescribe cocaine and other stimulants for that purpose,[20] the Attorney General would be powerless to take any action against them. In the majority's understanding of the Controlled Substances Act, the States are the ultimate arbiters of what qualifies as a "legitimate medical purpose."

Providing Recreation

No State allows controlled substances to be used for recreational purposes. Any registrant who dispenses controlled substances for such purposes may be prosecuted under the Controlled Substances Act, *see United States v. Henry*, 727 F.2d 1373, 1374 (5th Cir. 1984), *on reh'g*, 749 F.2d 203 (5th Cir. 1984) (*en banc*), and have his federal registration suspended or revoked. Yet, if a State decided to authorize physicians to prescribe controlled substances (*e.g.*, narcotics or barbiturates) for those purposes, the Attorney General would be powerless to take any action any against them.

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[19] By "euphoria," *amicus* means "a sense of intense stimulation, and of psychic and physical well-being." *United States v. Whitley*, 734 F.2d 1129, 1140 (6th Cir. 1984).

[20] Although classified as a narcotic, 21 U.S.C.§ 812(c), Schedule II(a)(4), 21 C.F.R. § 1308.12(b)(4) (2004), cocaine is a stimulant, not a depressant. *See United States v. Whitley*, *supra*, n. 12, 734 F.2d at 1140; *United States v. Castro*, 401 F.Supp. 120, 123 (N.D. Ill. 1975) (noting that, in the pharmacological sense, cocaine is "universally identified with amphetamines," and is "generally considered as an anti-fatigue, anti-soporific stimulant often used to stimulate alertness or euphoria).

Operating Unauthorized Narcotic Drugs Maintenance Programs

The Act authorizes practitioners to dispense narcotic drugs for maintenance treatment. 21 U.S.C. § 823(g) (Supp. 2005). Except in narrowly defined circumstances not involving Schedule II drugs, however, the statute provides "that every practitioner who dispenses narcotics for maintenance treatment must obtain a separate registration, the issuance of which is conditioned upon standards established by the Secretary of Health and Human Services and the Attorney General of the United States." *Luna v. Harris*, 888 F.2d 949, 953 (2nd Cir. 1989). Even with respect to Schedule III, IV and V narcotic drugs, practitioners who dispense drugs to individuals for maintenance treatment must comply with a myriad of statutory and regulatory requirements. *See*, *e.g.*, 21 U.S.C. §§ 823(g)(2)(B)-(D); 21 C.F.R. §§ 1304.03(c), 1304.03(d), 1304.04(f),1304.24, 1304.25, 1306.07(a)(2004). If a practitioner does not have a separate registration to dispense narcotics for maintenance treatment and dispenses Schedule III, IV or V narcotic drugs for such treatment in violation of §§ 823(g)(2)(B)-(D), the Attorney General may, for purposes of § 824(a)(4), "consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section [823(f)] to be inconsistent with the public interest." 21 U.S.C. § 823(g)(2)(E)(i).

Under the court of appeals' holding, a State could effectively nullify the elaborate federal regulatory framework for narcotic drugs maintenance programs by authorizing its own maintenance program without any of the safeguards built into the federal structure. The abuse of unregulated (or inadequately regulated) drug maintenance programs has been well documented. *See Luna*, *supra*, 888 F.2d at 953-54 (noting Congressional concern with the illegal diversion of

methadone used in drug maintenance programs); *United States v. Moore*, 423 U.S. 122, 126 (1975) (noting physician's unorthodox and unapproved method of treating heroin addicts by "saturat[ing]" them with such large quantities of methadone that "heroin would have no [physical] effect" on them and they would develop "a strong psychological desire for detoxification"). *See also Cushing v. Moore*, 783 F.Supp. 727, 729 (N.D.N.Y. 1992) (describing regulatory scheme), *aff'd as modified*, 970 F.2d 1103 (2nd Cir. 1992).

Prior to the court of appeals' decision in this case, it was generally understood that "under the guise of treatment a physician [could not] distribute drugs intended to cater to cravings of an addict." *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) (methadone), citing, *inter alia*, *Jin Fuey Moy v. United States*, 254 U.S. 189, 193 (1920) (morphine sulfate); *Webb v. United States*, 249 U.S. 96, 99-100 (1919) (morphine); *United States v. Behrman*, 258 U.S. 280, 288-89 (1922) (heroin, morphine and cocaine). *See also McBride v. United States*, 225 F.2d 249, 253 (5th Cir. 1955) (codeine). That understanding has been called into question by the Ninth Circuit's opinion.

Conducting Unregulated Research

The Controlled Substances Act allows practitioners to conduct research (including dispensing drugs) with Schedule I controlled substances under strictly defined conditions. The practitioner must be separately registered under the Act; his qualifications and competence must be evaluated by the Secretary of Health and Human Services; and the Secretary must assess the relative merits of the proposed research protocol in consultation with the Attorney General regarding "effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or

scientific use." 21 U.S.C. § 823(f). *See also* 21 C.F.R. §§ 1301.18, 1301.22, 1304.22(c) (2004). Even if the Secretary has deemed the practitioner is qualified to conduct research with Schedule I controlled substances, the Attorney General may deny his registration on one of the grounds specified in § 824(a) of the Act. 21 U.S.C. § 823(f).

Section 824(a)(4) authorizes the Attorney General to suspend or revoke a registration upon a finding that the registrant "has committed such acts as would render his registration under section 823 . . . inconsistent with the public interest as determined under such section." 21 U.S.C. § 824(a)(4). In determining "the public interest" under § 823, the Attorney General must consider five factors, the last of which is "conduct which may threaten the public health and safety." 21 U.S.C. § 823(f)(5). The court of appeals, however, denied that the Attorney General could suspend or revoke (or deny) "health care practitioners' DEA registrations" solely on this basis. 368 F.2d at 1129.[21] In light of the Ninth Circuit's exegesis of the legislative history, the Attorney General could not refuse to register a practitioner to conduct research with Schedule I controlled substances even if he determined that registration for that purpose would be inconsistent with the public interest because of conduct that might threaten the public health and safety.

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[21] *See also* Or. Br. in Op. 14 ("the 1984 amendments to the CSA [which added the cited language] were not intended to broaden the Attorney General's authority by permitting him to sanction physicians *whose conduct conformed to state laws*") (emphasis added). The legislative history cited by the majority and Oregon, *see* S. Rep. No. 98-225 at 267, 98th Cong., 2nd Sess. (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449, does not support this proposition. The requirement that the Attorney General *consider* all five factors does not mean that he must *find* that all five factors are present in order to deny an application for registration or suspend or revoke an existing registration.

Under current law, Schedule I controlled substances may be dispensed only in "federally approved research projects." *Fry v. D.E.A.*, 353 F.2d 1041, 1042 n.1 (9th Cir. 2003-). *See also United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 490 (2001) (for marijuana and other Schedule I controlled substances, "there is but one exception, and it is available only for Government approved research projects"). The court of appeals' crabbed reading of the Attorney General's authority under the Controlled Substances Act, combined with its inappropriate invocation of the "plain statement" rule of *Gregory v. Ashcroft*, effectively overturns the present federal restrictions on research with Schedule I substances.

The Ninth Circuit's holding in this case may be fairly summarized in a single sentence: So long as a controlled substance has *some* legitimate medical purpose, which all substances classified under Schedule II through V do have, a State may authorize its use for *any* purpose, no matter how unethical, unorthodox, untested or unusual, and the Attorney General would be powerless to take any action under the Controlled Substances Act against any registrant who had acted in accord with state law.[22] As the foregoing examples show, the court of appeals' holding would emasculate the Attorney General's authority to enforce the Act in a consistent, principled and uniform manner, and subject federal drug control policy to the vagaries of a patchwork of inconsistent state laws. Such an extraordinary result cannot be one required by a proper interpretation of the Act. The judgment of the court of appeals should be reversed.

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[22] For the reasons explained above, the court's holding even affects the Government's authority to regulate research (including dispensing drugs to human subjects) with Schedule I drugs, for which there is *no* recognized legitimate medical purpose.

CONCLUSION

For foregoing reasons, *amicus curiae*, the Thomas More Society respectfuliy requests that this Honorable Court reverse the judgment of the Court of Appeals.

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